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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,479	06/26/2003	Lawrence S. Young	HARR0032-101	5440

34139 7590 02/22/2006

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EXAMINER	
PRIEBE, SCOTT DAVID	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,479	YOUNG ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 4-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 4-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20060106*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 2, and 4-31 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action of 7/6/05 because the specification, while being enabling for making and using constructs comprising an expressible gene that is useful for treatment of cancer that is characterized by deregulation of the Wnt signaling pathway or the presence of TCF/β-catenin heterodimers, and for methods of treating cancer associated with deregulation of the Wnt signaling pathway or the presence of TCF/β-catenin heterodimers does not reasonably provide enablement for making and using constructs with expressible genes useful for treatment of diseases or methods of treating diseases other than cancer characterized by deregulation of the Wnt signaling pathway or the presence of TCF/β-catenin heterodimers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed 1/6/06 have been fully considered but they are not persuasive. Applicant incorrectly characterizes the rejection as indicating TCF/β-catenin heterodimers are present only in cancer cells, and provides evidence from documents published well after the time the instant invention was made that other diseases than cancer involve elevated β-catenin levels. In response, the grounds of rejection (page 6) correctly pointed out the fact that the specification did not identify any disease other than cancer as being "characterized

by the presence of TCF/β-catenin heterodimers," and that the prior art of record also disclosed no such disease other than cancer. Applicant has not disputed that the instant specification fails to describe any disease other than cancer that can be treated with the claimed invention. Applicant asserts that the fact the cited "references post-date the earliest effective filing date of the present application" is of no moment because the specification discloses how to make and use the constructs claimed. In response, it is not disputed that the specification teaches how to treat cancer characterized by "characterized by the presence of TCF/β-catenin heterodimers." However, the claims are not limited to the use of the claimed invention in treating such cancer. Applicant fails to indicate where the specification teaches how to make the requisite constructs for treating diseases other than cancer, much less teaches how to use such constructs to treat such diseases. "Argument of counsel cannot take the place of evidence lacking in the record." *In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974).

The issue is not whether one knows how to make a construct containing the TCF binding element, but knows what other elements should be included in the construct, first and foremost the "expressible gene is useful for treatment of" such a disease other than cancer, and knows how to use the construct to treat the disease other than cancer. Except for cancer, the specification and prior art of record are devoid of the teachings necessary to carry out the invention commensurate with the scope of the claims.

Finally, Applicant asserts that the Office "has unnecessarily read a limitation into the claims", i.e. treatment of cancer. In response, had the Office done so, there would have been no rejection. The rejection is based on the undue breadth of the claims relative to the far more limited guidance in the specification and prior art, i.e. treatment of more than cancer. Applicant

asserts that there is no requirement for guidance or a working example in the specification in order to meet the enablement requirement, and implies that Applicant is being improperly limited to preferred embodiments. In response, while there is no absolute requirement that the specification contain guidance or working examples, such lack is evidence for a lack of enablement. The issue is not one of limiting the claims to preferred embodiments, but one of rejecting the claims based on the undue experimentation required to practice the claimed invention as broadly as it is claimed. A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. Tossing out the germ of an idea does not constitute an enabling disclosure. While every aspect of a generic claim need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable the skilled artisan to understand and carry out the invention. ...When there is no disclosure of the specific starting materials or conditions under which the process can be carried out, there is a failure to meet the enablement requirement. See *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997). The instant application fails to disclose the specific starting materials or conditions for treating diseases other than cancer.

Claims 4-8, 20-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 7, 20, 21, 23, and 26 each recite the limitation "[T/t]he nucleic acid construct of any one of claims 1 to 3". There is insufficient antecedent basis for this limitation in the claim;

claims 1 and 3 have been cancelled. The remaining rejected claims indirectly recite the limitation through their dependence on one of claims 4, 7, 20, 21, 23, and 26.

Double Patenting

Claims 2 and 4-31 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,608,037 for the reasons of record set forth in the Office action of 7/6/05. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace the subject matter of the patented claims.

Applicant has indicated that a terminal disclaimer will be filed upon an indication that the claims are otherwise allowable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633